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| APPLICATION NO.                                                                       | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.          | CONFIRMATION NO. |
|---------------------------------------------------------------------------------------|-------------|----------------------|------------------------------|------------------|
| 09/750,739                                                                            | 12/29/2000  | Timothy J. Nichols   | P-8863                       | 7216             |
| 27581                                                                                 | 7590        | 07/14/2004           | EXAMINER                     |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARKWAY NE<br>MS-LC340<br>MINNEAPOLIS, MN 55432-5604 |             |                      | SUKHAPHADHANA, CHRISTOPHER T |                  |
|                                                                                       |             |                      | ART UNIT                     | PAPER NUMBER     |
|                                                                                       |             |                      | 2625                         | <i>12</i>        |
| DATE MAILED: 07/14/2004                                                               |             |                      |                              |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                              |                |
|------------------------------|------------------------------|----------------|
| <b>Office Action Summary</b> | Application No.              | Applicant(s)   |
|                              | 09/750,739                   | NICHOLS ET AL. |
|                              | Examiner                     | Art Unit       |
|                              | Christopher T. Sukhaphadhana | 2625           |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 19 May 2004.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-15 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 19 May 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Response to Amendment*

1. The Amendment filed 19 May 2004 has been entered in full.
2. Based on Applicant's amendments, the objections to the claims are withdrawn.

### *Drawings*

3. The drawings were received on 19 May 2004. These drawings are acceptable.
4. Based on Applicant's formal drawings, the objections to the drawings are withdrawn.

### *Response to Arguments*

5. Applicant's arguments, see the last paragraph on page 6 of the Amendment filed 19 May 2004, with respect to the rejection(s) of claim(s) 1-15 under prior art have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the previously applied prior art in further combination with Seeley (U.S. Patent 6,615,191 B1).

### *Claim Objections*

6. **Claims 1-7** are objected to because of the following informalities: The "memory associated with the implanted medical device" limitation is recited twice in **claim 1**. **Claims 2-7** contain objected to language inherited from claim 1. Appropriate correction is required. In regards to application of prior art, the Examiner will treat the claims as if the limitation were recited only once.

*Claim Rejections - 35 USC § 112*

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. **Claims 13-15** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

9. In regards to **claim 13**, Examiner has been unable to locate where in the specification a method comprising: granting a qualified access; and determining whether the potential user is requesting access associated with an override function is described. Lines 16-24 on page 9 of the specification describe determining whether the potential user is requesting access associated with an override function, but only in the context where granting qualified access has been denied (step 504 and 507, Fig 5).

10. **Claims 14 and 15** inherit language from claim 13.

*Claim Rejections - 35 USC § 103*

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. As best understood in light of the claim objections and rejections under 35 USC 112, **claims 1-9 and 11-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, previously cited, "Smith") in combination with Piosenka et al (U.S. Patent 4,993,068, previously cited, "Piosenka") and Seeley (U.S. Patent 6,615,191 B1, newly cited, "Seeley").

13. In regards to **claim 1**, Smith discloses a user recognition system (Fig 1) to identify a user and enable access to instruments associated with at least one implanted medical device, the system comprising: an implanted medical device (ref no 20, Fig 1, and col 11, line 30) in a patient; a memory associated with the implanted medical device (ref no 40, Fig 1); an instrument (col 11, line 31) in data communications with the implanted medical device; and an analyzer unit (col 11, lines 40-44) determining whether a potential user is authorized to have access to the data communications of the instrument.

Smith does not expressly disclose a sensor unit positioned along the instrument for generating biometric traits of the user.

However, Smith discloses a user recognition system submitting a password, or series of passwords, that are known only to field clinical engineers, or others, who are authorized and have sufficient training to be able to replace the control program (col 11, lines 40-44).

Piosenka teaches a sensor unit positioned along the instrument for generating biometric traits of the user (ref no 20-25, Fig 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Piosenka's sensor unit for generating biometric traits in lieu of Smith's passwords

because it provides a system that is not defeated by extracting "known" information (e.g. passwords) from the rightful user allowing a fraudulent user to pose as the rightful user (Piosenka, col 1, lines 51-53, see also first two paragraphs of Summary of the Invention).

Smith and Piosenka do not expressly disclose the analyzer unit wherein, in response to the potential user not being authorized to have access, the analyzer unit determining whether the potential user is requesting access associated with an override function.

Seeley teaches, in the paragraph bridging col 8 and 9, in response to a potential user not being authorized to have access, the analyzer unit determines whether the potential user is requesting access associated with an override function.

Seeley and Smith and Piosenka are combinable because they are from the art of access verification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka to obtain the invention as recited.

14. In regards to **claim 2**, Smith further discloses in col 11, line 30, said implanted medical device including a pacer.

15. In regards to **claim 3**, Smith further discloses in col 11, line 31, said instrument including a programmer.

16. In regards to **claim 4**, Piosenka further discloses in refs no 11-15, Fig 1, said user recognition system including a finger scanner, a camera, and a microphone.

17. In regards to **claim 5**, Piosenka further discloses in ref no 13, Fig 1, said biometric traits include a finger scan obtained from said finger scanner.

18. In regards to **claim 6**, Piosenka further discloses in ref no 12, Fig 1, said biometric traits include a retina scan obtained via said camera.

19. In regards to **claim 7**, Piosenka further discloses in ref no 14, Fig 1, said biometric traits including a voice print obtained from said microphone.

20. In regards to **claim 8**, Smith discloses a user authentication system (Fig 3) for identifying and granting access (ref no 301, Fig 3) to at least one user (col 11, lines 40-44) to an implanted medical device (col 11, line 31) in a patient associated with an instrument (ref no 46, Fig 1).

Smith does not expressly disclose the remaining limitations of the claim.

However, Smith discloses the user authentication system submitting a password, or series of passwords, that are known only to field clinical engineers, or others, who are authorized and have sufficient training to be able to replace the control program (col 11, lines 40-44).

Piosenka teaches a biometric-based user authentication system (Fig 1) for identifying and granting access to at least one user associated with an instrument (ref no 1, Fig 1), the authentication system comprising: at least one biometric sensor (ref no 11-15, Fig 1) implemented in the instrument; at least one biometric trait of a user stored as coded data (col 8, lines 10-32) in a memory bank of said biometric sensor; and means for analyzing and comparing (col 8, lines 33-68) said at least one biometric trait with said coded data to grant or deny access.

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Piosenka's biometric-based user authentication system into Smith's external programmer 46 because it provides a system that is not defeated by extracting "known" information (e.g. passwords) from the rightful user allowing a fraudulent user to pose as the rightful user (Piosenka, col 1, lines 51-53, see also first two paragraphs of Summary of the Invention).

Smith and Piosenka do not expressly disclose the means for analyzing wherein, in response to the potential user not being denied access, the analyzing means determining whether the potential user is requesting access associated with an override function.

Seeley teaches, in the paragraph bridging col 8 and 9, in response to a potential user not being authorized to have access, the analyzing means determines whether the potential user is requesting access associated with an override function.

Seeley and Smith and Piosenka are combinable because they are from the art of access verification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka to obtain the invention as recited.

21. In regards to **claim 9**, Piosenka further discloses in refs no 11-15, Fig 1, said at least one biometric sensor including a camera, a finger print sensor, and a microphone.

22. In regards to **claim 11**, Smith further discloses in col 11, lines 28-44, said means for analyzing and comparing includes a software system implemented in the memory bank of the sensor.

23. In regards to **claim 12**, Smith further discloses in col 11, lines 44, "replace the control program", the biometric traits of the user stored as coded data includes instructions to allow a user with matching traits to have access to a pre-determined set of data and tools of said implanted medical device.

24. In regards to **claim 13**, Smith discloses a method for an identification system of a user (Fig 3) to provide authorized access (ref no 301, Fig 3) to operational hardware, software and patient medical data (ref no 301, Fig 3) contained in instruments and implanted medical devices (col 11, line 31).

Smith does not expressly disclose the remaining limitations of the claim.

Piosenka teaches a method for a biometric-based identification of a user (Fig 1) to provide authorized access, the method comprising: accepting at least one biometric trait from a potential user (ref no 11-15, Fig 1, and col 8, lines 33-47); comparing said at least one biometric trait to a stored coded data (col 8, lines 48-68); and granting a qualified access when a match is confirmed between said at least one biometric trait and the stored coded data (col 8, line 67).

Smith and Piosenka do not expressly disclose determining whether the potential user is requesting access associated with an override function.

Seeley teaches, in the paragraph bridging col 8 and 9, determining whether the potential user is requesting access associated with an override function.

Seeley and Smith and Piosenka are combinable because they are from the art of access verification.

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Seeley's override function into Smith and Piosenka's system.

The suggestion/motivation would have been to provide access in the case of an injured finger that is not recognized by the match detector (Seeley, col 9, line 3).

Therefore, it would have been obvious to combine Seeley, Smith, and Piosenka to obtain the invention as recited.

25. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith"), Piosenka et al (U.S. Patent 4,993,068, "Piosenka"), and Seeley (U.S. Patent 6,615,191 B1, "Seeley"), as applied to claim 8 above, in further combination with Clayden (U.S. Patent 5,787,185, newly cited, "Clayden").

26. In regards to **claim 10**, Piosenka further discloses said at least one biometric trait of a user including a fingerprint (ref no 13, Fig 1), a voice print (ref no 14, Fig 1), a retinal print (ref no 12, Fig 1), a facial model (facial photo, abstract), and a digital signature (ref no 15, Fig 1).

Smith, Piosenka, and Seeley do not expressly disclose including a veinal imprint.

Clayden teaches biometric identification using veinal imprint (col 2, lines 7-18).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Clayden's veinal imprint into Smith, Piosenka, and Seeley's system because Clayden's method is an improved method of verifying the identity of individuals (Clayden, col 1, line 33).

27. **Claims 14 and 15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, Jr. et al (U.S. Patent 5,456,692, "Smith"), Piosenka et al (U.S. Patent 4,993,068, "Piosenka"), and Seeley (U.S. Patent 6,615,191 B1, "Seeley"), as applied to claim 13 above, in further combination with Freed et al (U.S. Patent 6,132,363, newly cited, "Freed").

28. In regards to **claim 14**, Smith, Piosenka, and Seeley do not expressly disclose said qualified access including a hierarchical scheme to enable user-specific access and authorization based on expertise and need.

Freed teaches a qualified access including a hierarchical scheme to enable user-specific access and authorization based on expertise and need (col 12, lines 1-8, and paragraphs bridging col 12-13).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Freed's teachings into Smith, Piosenka, and Seeley's method because it insures security (Freed, col 11, line 63) and minimizes inadvertent changes to settings that should be factory adjustable only (Freed, col 12, line 7).

29. In regards to **claim 15**, Freed further discloses in the paragraphs bridging col 12-13, the hierarchical scheme including distinctions of access to various hardware, software tools to perform therapy, diagnose and monitoring functions designed to provide various levels of authorized access to physicians, nurses, technicians, patients, and their representatives.

*Conclusion*

30. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

31. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher T. Sukhaphadhana whose telephone number is (703) 306-4148. The examiner can normally be reached on 9a-5p M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh M. Mehta can be reached on (703) 308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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